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depending upon the cost of the medication being prior authorized relative to alternative formulary medications within the same therapeutic class of drugs.

A step therapy protocol may require a physician to prescribe older and less expensive drugs in a therapeutic class before prescribing newer and more expensive equivalents.

Pharmacy's Relationship with Pharmaceutical Manufacturers

Pharmacy retailers have minimal control over which drug product is dispensed and minimal impact on influencing the market share of a given drug product because a drug product's selection is primarily directed by formularies or preferred drug lists generated by PBMs.

PBMs, through the use of their formularies, manage about 70% of the more than 3 billion prescriptions dispensed in the U.S. annually.⁵⁴

⁵⁴ Finding of 2003 GAO Report on Federal Employee Health Benefits Plan (FEHBP).

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Physicians

Managed care's effect upon the physician

The pre-managed care market:

Prior to the mid-1980's managed care played a marginal role in health care underwriting. Indemnity insurance covered most of the employer sponsored health insurance benefit market and managed care was not a factor in government entitlement programs at either the state or the federal level.

Physicians cared for their patients and prescribed pharmaceuticals based upon their experience and training. While physicians were "detailed" by most of the brand pharmaceutical manufacturing companies' sales forces, there were no physician-directed or health insurance company financial inducements to preferentially select a particular drug.

Prior to online adjudication, there was no readily available performance data available to the manufacturer to use in targeting specific physicians. Today this targeting is based upon prior prescribing patterns distributed regularly, usually by quarter or by month, from data vendors such as IMS.⁵⁵

Patients took the physician's prescription to the pharmacy and the pharmacist dispensed the drug. Pharmacies stocked products based upon the prescribing patterns of the physicians in their immediate market. Pharmaceutical manufacturers played little role in influencing the inventory carried by dispensing pharmacies.

Frequently, pharmacists and physicians would confer concerning the most appropriate drug to administer to the patient. The patient then paid for the medication out of his or her own pocket.

The managed care dominated market:

All of the above changed starting in the later half of the 80's, managed care evolved into the dominant form of underwriting in both group health coverage and much of the state and federal entitlement markets. In 1976 there were six million people enrolled in HMOs. By 1995 that number had reached 58.2 million.⁵⁶ In 1960 public and private expenditures on health care amounted to \$26.8 billion; by 1994 this amount had grown to \$949.4 billion. Spending for pharmaceuticals accounted for 8.2% of this total.⁵⁷

This rapid inflation in medical spending, relative to the general consumer inflation rate, caused a paradigm shift in healthcare insurance from fee-for-service reimbursement to a managed care dominated market.

This transition introduced a third party whose financial performance was dependent upon confining the decision-making parameters for both physicians and pharmacists. Neither the prescriber nor the dispenser of medications worked solely for the patient any

⁵⁵ <http://www.imshealth.com/ims/portal/pages/homeFlash/us/0,2764,6599,00.html>

⁵⁶ Medical Interface's Facts & Figures, Bronxville, New York, Medicom International 1996.

⁵⁷ Medical Interface's Facts & Figures, Bronxville, New York, Medicom International 1996.

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longer. They also answered to MCOs with management structures that became more complex and distant each year.

Prescribing Medications in the Managed Care Environment

Over the past two decades, the business environment in healthcare has been transformed into a complex and, for the physician, incomprehensible third party payor system. Insurance intermediaries have launched complex managed care products, including a wide variety of pharmacy benefits structures, into the market. These intermediaries then turn to the physician and expect him/her to manage these benefits in the ambulatory environment without any information system infrastructure to accomplish this assignment.

How the pharmacy benefit impacts physician decision making

The National Drug Code Directory⁵⁸ lists fourteen major drug classes with each containing multiple subclasses. Over fifty-one thousand drug products are listed in this classification system.⁵⁹ Between 1975 and 1999, 548 new chemical entities were approved by the FDA as prescription drugs.^{60,61}

Formularies are organized by the classes and subclasses described in the National Drug Code Directory. Each formulary generally provides at least one medication for each of these classifications. Any of these "favored" drugs is subject to change based upon the PBM's contractual relationships with the various manufacturers. In fact, any printed formulary that is distributed to physician offices by an insurance company is generally outdated the month it is delivered. The "favored" or "preferred" drugs are frequently different for each PBM / MCO and often for each of the PBM's / MCO's clients.

From the physician's perspective, formularies represent an incomprehensible listing of drugs that are "favored" by the underwriter of the pharmacy benefit. Physicians soon learned that formularies are not intuitive. That means that different drugs are "favored" not based on data in the peer-reviewed scientific literature but based on business considerations.

On average, a physician deals with more than six different drug formularies daily.^{62,63} Each formulary has different "favored" drugs; the practicing physician is expected to

⁵⁸ The NDC System was originally established as an essential part of an out-of-hospital drug reimbursement program under Medicare. The NDC serves as a universal product identifier for human drugs. The current edition of the National Drug Code Directory is limited to prescription drugs and a few selected OTC products.

⁵⁹ The major drug class is a general therapeutic or pharmacological classification scheme for drug products reported to the FDA under the provisions of the Drug Listing Act. The classification scheme used was based on the AMA DRUG EVALUATIONS SUBSCRIPTION and generally follows the organization of material in that publication. The drug class for each product was determined by the labeled indication.

⁶⁰ Safety of Newly Approved Drugs: Implications for Prescribing; Robert J. Temple, MD; Martin H. Himmel, MD, MPH; JAMA / volume:287 (page: 2273); May 1, 2002

⁶¹ Timing of New Black Box Warnings and Withdrawals for Prescription Medications; Karen E. Lasser, MD, MPH; Paul D. Allen, MD, MPH; Steffie J. Woolhandler, MD, MPH; David U. Himmelstein, MD; Sidney M. Wolfe, MD; David H. Bor, MD; JAMA / volume:287 (page: 2215); May 1, 2002

⁶² Minnesota Medicine, January 2001/Vol 84.

⁶³ Minnesota Medicine, January 2001/Vol 84.

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know the "favored" drug and the co-payment structures for hundreds of different major and minor drug classes.

The prescribing process

The following chart summarizes the various tools used by PBMs to influence physician decision making within the managed care environment.⁶⁴

HMO Use of Management Strategies to Affect Physician Prescribing by Line of Business				
Physician Prescribing Incentives	Commercial/Group	Medicaid	Medicare	Overall
Prior Authorization	94.1%	82.9%	81.4%	88.3%
Physician Education Programs	88.1%	80.0%	86.1%	85.3%
Physician Prescribing Profile/Report Cards	81.0%	64.7%	76.7%	76.1%
Physician Financial Incentives	34.9%	31.3%	38.1%	35.0%
Physician Capitated for Pharmacy	25.3%	21.9%	38.1%	28.0%
Physician Financial Penalties	19.3%	9.4%	19.1%	17.2%

Source: Novartis Pharmacy Benefit Report.

Emron IMS HEALTH

Managing the dispensing and use of pharmaceuticals represents a major time commitment for physicians in practice. A typical primary care doctor writes as many as 30 prescriptions or more daily and handles an equal number of prescription renewals.⁶⁵

Within managed care, the prescribing process can best be described as classic Pavlovian pain avoidance conditioning for most practicing physicians. The average primary care physician spends 40 minutes a day on managed care (mostly around referral and prescription issues).⁶⁶

Both formulary compliance calls and renewals, usually triggered by a call from the pharmacist, are particularly time consuming. Sixty-one percent of doctors who were questioned said insurance plans (MCOs/PBMs) denied coverage for a prescription drug for one of their patients on a weekly basis.⁶⁷ Studies of doctors' offices⁶⁸ found that

⁶⁴ Novartis Pharmacy Benefit Report 2000.

⁶⁵ Proprietary data (various dotcoms, RxPhysician.com, IMS & various PBMs).

⁶⁶ *The Western Journal of Medicine*; March, 2001.

⁶⁷ Studies of doctors' offices by Merck-Medco, 1998

⁶⁸ Studies of doctors' offices by Merck-Medco, 1998

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nurses on average spend 80 percent of their time handling prescriptions. For doctors, the average is 30 minutes or more per day.⁶⁹

More than half of the clinical calls to doctors concern pharmacy issues centering upon refills and formulary issues.⁷⁰ To handle a pharmacy call, the physician's staff must pull the patient's chart. On average, every chart in a doctor's office is pulled 6.5 times each year. Each chart pull generates 3 hours of overhead and costs \$5 to \$7 or more per hour.⁷¹

Traditionally, PBMs have used mailings, faxes and phone calls to contact doctors. Merck-Medco Managed Care made about 2 million phone calls to doctors' offices in the course of managing 322 million prescriptions, according to the company. While the above is generally viewed negatively by physicians, it should be said that most physicians welcome drug-utilization data such as how their prescribing habits compare with national benchmarks.

Prescribing a non-"favored" drug will produce significant discomfort for a practicing physician. He/she will often receive a phone call from the dispensing pharmacist usually informing him/her that his/her patient is standing at the counter, in some distress, and the medication the physician prescribed is not covered. To get the patient the non-covered drug he/she prescribed, the physician must fill out a "prior-authorization" form and send it to the PBM processing the pharmaceutical claim.

Because each PBM or MCO has a different form, most physicians do not have the right form in their office. Getting the form requires calling the PBM and having them fax the form to the physician's office. Unless the form is fully and accurately filled out, the claim is denied.

Given the above, over 93% of practicing physicians indicate that it is either difficult or extremely difficult to obtain coverage for a non-formulary drug for their patients.⁷² As a result, most physicians are exasperated by the time dedicated to PA paperwork. Physicians are reporting that they now routinely fill out up to 10 prior authorization forms a day.⁷³

Community pharmacists, who are on the receiving end of this transaction, complain about the administrative burden of PA programs as well. On average, a supermarket chain pharmacy spends 2.15 minutes and an independent pharmacy spent 2.97 minutes just on rejection resolution for each prescription that required a prior authorization.⁷⁴

After experiencing the above chain of events, few physicians will try to get an off formulary or a non-preferred drug for their patient even if they feel an alternative is more efficacious and is indicated for the patient's clinical condition.

In addition to all of the above, if physicians consistently prescribe off formulary, they are flagged by the PBM for individual attention and instruction.

⁶⁹ *Hospitals & Health Networks*, Michael Menduno, July 1999.

⁷⁰ *Hospitals & Health Networks*, Michael Menduno, July 1999.

⁷¹ *Hospitals & Health Networks*, Michael Menduno, July 1999.

⁷² *Minnesota Medicine*, January 2001/Vol 84.

⁷³ Personal conversations with physicians in multiple markets across the United States.

⁷⁴ Herrier RN, Spencer JR, Davis CD. Case study using descriptive analysis to estimate hidden costs in processing third party prescriptions. *J Am Pharm Assoc* 2000; 40(5): 658-65

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For example, the Medco Contract provides: "Physicians representing a minimum of ninety (90%) percent of prescriptions written for competing branded oral estrogens dispensed at retail for (health plan) members will be contacted (by telephone or written correspondence referring to Premarin, other than simply mailing the formulary) by Medco, as medically appropriate, at least once per Contract Quarter to advise them of Premarin's preferred formulary status. Failure by Medco to contact physicians as required above in any Contract Quarter will result in a reduction in rebates to Medco for Premarin dispensed at retail in the subsequent Contract Quarter."⁷⁵

As a result, PBMs have become proactive in their management of the formulary with physicians. Merck-Medco Managed Care made about 2 million phone calls to doctors' offices during the course of a year in the processing of 322 million prescriptions.⁷⁶ The company also uses e-mail to contact doctors as an "adjunct" to its normal mailings and phone calls.

All of the above equates to pain for the physician. Since no human being can keep up with all the variables that go into formulary maintenance described above, the physician tends to identify the drugs he commonly prescribes (generally 20 to 40 medications)⁷⁷ based on whether they are included in the major contracts they service.

This latter phenomenon is referred to within the industry as the "spillover" effect. It is known that if a pharmaceutical manufacturer succeeds in getting their products classified as preferred on the major PBM formularies, then the physician will likely begin using that product on all of his/her patients. When prescribing for self pay patients, where there are no managed care barriers to selecting alternatives, physicians will generally prescribe the on formulary drug.

Physicians and the Prescribing Process^{78,79}

A comprehensive evaluation of the physician's view of the prescribing process was performed by California Health Decisions with their publishing the results of their research in June of 2001.⁸⁰

The report examined a series of issues including physicians' experiences when prescribing medications. The following information, extracted from this report, deals with this issue.

⁷⁵ WYE 006084 – 6.1.1

⁷⁶ AMNews; Carolyn Hirschman; June 28, 1999. [/public/journals/amnews/amnews.htm](http://public/journals/amnews/amnews.htm)

⁷⁷ Proprietary data (dot.coms, RxPhysician.com, IMS & various PBMs).

⁷⁸ California Health Decisions' (CHD's) Healthcare 101 project. The purpose of the report is to describe survey research conducted with 81 California primary care physicians. The analysis examines their views on prescription medication issues and identifies differences and similarities among physician and consumer opinions.

⁷⁹ The Seattle-based firm Endresen Research was commissioned by CHD to participate in designing the survey and to carry it out. A total of 1,154 primary care physicians received a letter from CHD explaining the research and inviting them to participate in an 18-minute phone survey. A total of 81 physicians completed the survey (7 percent response rate). The survey sample included physicians from northern and southern California who contract with PacifiCare, Blue Shield, and HealthNet, as well as those employed by Kaiser Permanente.

⁸⁰ California Health Decisions (CHD) is a non-profit organization dedicated to involving the public in policies and practices decisions that affect their healthcare. CHD, which is affiliated with American Health Decisions, was founded in 1985.

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- Specific concerns cited include obtaining approvals for formulary exceptions, named as a "major problem" by nearly 68 percent of those surveyed.
- Access to formularies for specific health plans was named a "major problem" by nearly two-thirds of physicians surveyed.
- More than one-third of physicians named "formulary restrictions" as the greatest source of frustration when asked to describe, in their own words, barriers or problems they experience with respect to prescription medications.

In an open-ended portion of the interview, physicians were asked how the formulary process could be improved.

- Several expressed the wish that formularies could be broadened to include more medications. "The formularies need to be opened up quite a bit to give more leeway to the physician," was one comment.
- In addition, providers would like to have readier access to health plans when formulary questions arise. "Waiting time for approval" was cited as frustrating, as was inability to reach the plan in a timely manner. As one physician put it simply, "Please answer the phone."
- Another physician would like to "speak directly to the doctor who is making the decisions" when coverage for a particular medication is at issue.
- Finally, several physicians remarked that keeping up with multiple formularies is burdensome, and suggested that standardization among plans, regions, or medical groups would smooth the process. "It takes too much time to go through individual listings from separate companies," noted one provider.

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Wyeth-Ayerst Laboratories, Inc.'s marketing Strategy

Wyeth (American Home Products, AHP) is one of the world's largest research-driven pharmaceutical and health care products companies. Wyeth employs in excess of 52,000 people worldwide, with their Pharmaceutical products division comprised of over 38,000 employees.

In 1999 Wyeth posted sales in excess of \$13 billion, listing their total assets in excess of \$23 billion. In 1999 Wyeth's Premarin family of products approached sales of \$1.8 billion, up 8 percent from year prior.⁶¹

In the United States Wyeth markets their pharmaceutical products and services directly to most all major constituents within the health care industry; pharmacy benefit management companies, managed care organizations, governmental agencies, physician groups and retail pharmacy organizations.

Wyeth Managed Care's documents indicate that formulary structure was of importance to the company.

The following represent a few examples:

- **(WYE 187812)** When discussing "availability" of competitive products on a three tier plan.
 1. All products are available, however
 2. Third tier is non-formulary (though) the patient can (get the drug) by paying more out of pocket for it.
 3. What that means is when a physician prescribes the non-formulary product; the patient has higher out-of-pocket costs. Thus the patient can get a Premarin Family product for a lower out of their pocket cost.
 4. Remind physicians and office staff that seniors pay more out of their pocket for non-formulary products.
 5. (By saving the patient money, the physicians office will) experience less callbacks and time spent switching patients.

⁶¹ www.wyeth.com

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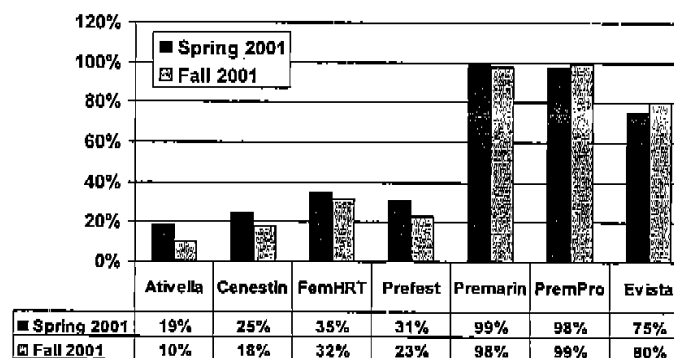
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(WYE 204989) – demonstrates the “formulary status for the Premarin Family and its competition” as of March 2001 for the various HRT/ERT products.

	Activella	Cenestin	Evista	Femhrt	Ortho Prefest	Premarin	Premphase	Prempro
On formulary	4.9%	9.9%	65.8%	31.5%	21.6%	99.2%	97.3%	97.8%
Not on formulary	95.1%	82.6%	22.2%	67.3%	77.2%	0.8%	2.7%	2.2%
Prior authorization	17.3%	21.6%	16.6%	15.1%	18.2%	0.6%	1.8%	1.5%
3 rd tier/ higher copay	97.0%	85.1%	33.8%	60.0%	65.0%	0.2%	3.2%	1.9%
Not listed on formulary but covered	27.4%	26.5%	7.6%	18.5%	21.6%	0.7%	0.6%	0.5%

- (WYE 203120-22) provides a bit more detail concerning the HRT/ERT formulary coverage as of the fall of 2001.
 - **Total on Formulary** – “This combines the total Rx eligible lives covered on formulary with prior authorization or restrictions and on formulary with no restrictions or prior authorization requirements. On formulary does not include third-tier co-payment status and can be interpreted that a product is available at second-tier or better.”

Total On Formulary % HMO Lives



Source: WYE 203122

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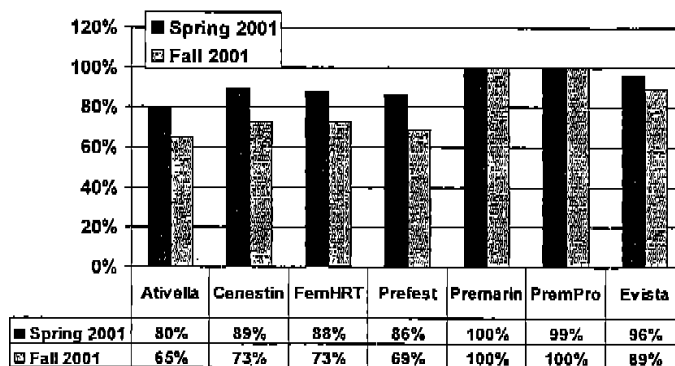
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Note: "Total On Formulary" does not include Rx eligible lives associated with a three-tier benefit design.

- "Total formulary coverage for the Premarin Family remained consistent between the spring and fall audit cycles while formulary coverage decreased for the majority of HRT/ERT products, excluding Evista. Evista experienced an increase in its formulary coverage, from 75% in the spring to 80% in the fall."⁸²
- **Total Coverage** – "This is the total Rx eligible lives covered by plans that list a drug on formulary plus the total number of plans that list a drug as non-formulary but still covered."

Total Coverage



Source: WYE 203122

- "Total coverage for the Premarin Family remained consistent between the spring and fall. Meanwhile, all remaining HRT/ERT products experienced a decrease in their total coverage of HMO members. Ortho-Prefest experienced the greatest decline in percentage of total coverage during the fall 2001 audit cycle."⁸³

⁸² WYE203121

⁸³ WYE203122

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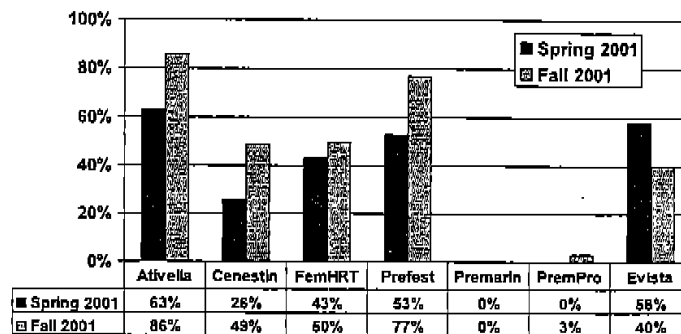
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- **Prior Authorization** – “The need for a physician or pharmacist to obtain prior approval from a health plan before coverage of the drug guaranteed.”

Prior Authorization



Source: WYE 203123

- “Overall, the Premarin Family continues to remain unaffected by HMOs’ prior authorization requirements. However, all competing products in the HRT/ERT market, excluding Evista, experienced an increase in their prior authorization coverage during fall 2001. Ortho-Prefest experienced the largest growth between audit cycles, in terms of prior authorization coverage.”⁸⁴

⁸⁴ WYE203123

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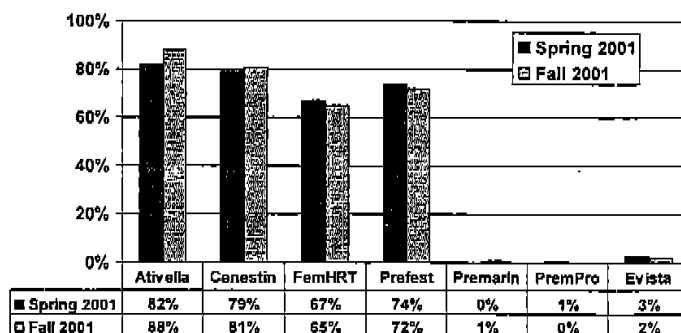
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- o **Covered at Third-Tier co-pay** – “A drug listed in a third tier. Health plan members enrolled in a three-tier benefit design must pay a higher co-pay for the drug.”

Covered at Third-Tier Co-Pay



Source: WYE 203124

- “The Premarin Family is not affected by three-tier coverage, unlike competing products within the market. With the exception of Evista, the majority of products within this market have a relatively high three tier co-pay status. Evista decreased its three-tier coverage between the two audit cycles, from 33% in the spring to 29% in the fall.”⁸⁵
- (AHP 366155) – The Scott-Levin Spring 2002 Managed Care Formulary Drug Audit is detailed in this confidential memorandum from the Managed Markets Customer Planning, 9/02 dated August 12, 2002.

The Women’s Health Initiative (WHI) did not affect the coverage of ET/HT products within the managed care formularies

- o The majority of health plans stated the WHI (Women’s Health Initiative) Cognitive findings that appeared in a recent JAMA article had no effect at all on the coverage of ET/HT products within their formularies.⁸⁶

⁸⁵ WYE203123

⁸⁶ “Premarin Diagnostic”; October, 2003; AHP 339064.

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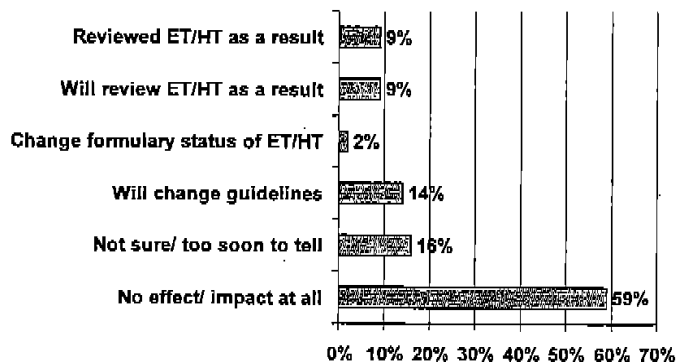
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Impact of WHI Cognitive Findings on ET/HT Coverage



Source: Custom MCO Panel – July 2003; AHP 339064.

The effect of tier positioning on a product's performance in the market.

The tier position for a product is of extreme importance. For example, Wyeth knew that in most occurrences of 2nd to 3rd tier position switches, the switched products lost substantial in-plan market share during the 6-12 month period immediately following the switch. Mitigating factors included brand loyalty, co-pay differentials, and restrictions.⁸⁷

The following graph illustrates the phenomenon of market contraction when Wyeth's ET/HT products lost their formulary preferred status in the Aetna account when Premarin was switched to the third tier in January 2003.⁸⁸

Aetna Pharmacy Management

	4Q 02	1Q 03	Difference	Percentage Decrease
Premarin Tab	8,179,191	6,435,965	-1,743,226	-21.31%
PremPhase Tab	311,234	214,394	-96,840	-31.11%
Prempro Tab	2,534,444	1,696,820	-837,624	-33.05%
All	11,024,869	8,347,179	-2,677,690	-24.29%

⁸⁷ Putnam Associates; The Premarin Family Pricing Project; August 21, 2002; AHP 256828

⁸⁸ AHP 343345

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The following summarizes the CIGNA data during this same time period. CIGNA did not change the formulary position for Premarin during this time period as Aetna had done.

- **(AHP 338598)** - October 2003 correspondence between Kate Eby Moore and Margaret Glassman (the memo indicates that Glassman is an analyst at Wyeth) with copies going to Betty Jean Swartz summarizes the analyst's assessment of the differing market performance for Premarin between the Aetna and the CIGNA account.
 - 10/10/03 Margaret Glassman queries Kate Moor – "...Looks like Aetna has had a significant decrease in P3 use -- significantly greater than similar plans. I'm also attaching, as a comparison, CIGNA's data from the same period. I chose CIGNA because 4Q 02 sales were very similar at \$8.5M/quarter and membership is fairly close: 7.5M members for Aetna, 8.5M for CIGNA."
 - Two hours later on 10/10/03 Kate Moor responds – "...If there was a 42% drop in sales, what part of that was the formulary issue and what part of that was the WHI? If you got back on formulary, how much is that worth a mo/qtr/year?"
 - Half an hour later, Glassman responds: "...Aetna decreased 42% while a similar plan, like CIGNA, only decreased 15%. I'm not sure if that means we can attribute the additional 30% decrease to Premarin being non-formulary at Aetna, but I'm sure a big portion of it is directly related to the \$15 higher co-pay. So before removal from formulary we sold \$8.5M/quarter and if the natural erosion due to WHI from 4Q 02 to 2Q 03 was only 15% we should still be selling 7.3M, yet our analysis indicates that we're actually only selling approximately 5M/quarter. In round numbers, our NF (non-formulary) status could be costing us \$8M/year."
 - Thus it would appear that Wyeth suffered both from the WHI report (15% loss in sales volume) and from the loss of the formulary preferred position in accounts such as Aetna (46% [= \$7.3/\$5] drop in sales volume). Clearly, the variable that affected Wyeth's market performance was the loss of preferred status on the formulary. In fact, the order of magnitude was roughly a factor of three.

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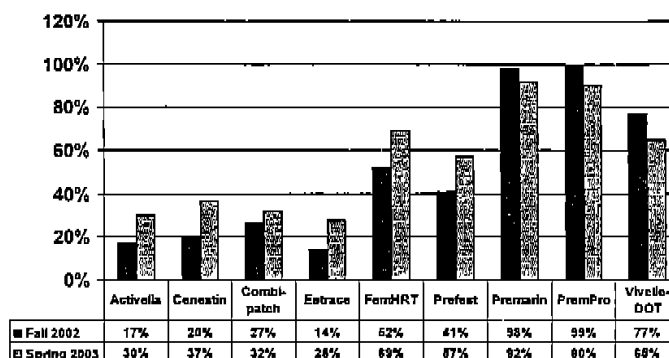
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- **(AHP 340336-41)** – The data updates the market information to the fall of 2002 and the spring of 2003 using a different source (Verispan's spring 2003 ET/HT Formulary Coverage Information) confirms the above findings.
 - **Total On Formulary** – “Total formulary coverage (considered 2nd tier or better) for Premarin decreased from 98% to 92% between the fall 2002 and Spring 2003 audit cycles while Prempro decreased from 99% to 90% during this same time period. FemHRT (52% to 69%) and Cenestin (20% to 37%) had the largest increases between the fall 2002 and spring 2003 audit cycles. Actively (17% to 30%) and Prefest (41% to 57%) also experienced large gains during this time period.”⁸⁹

ET/HT Market
 Total on formulary (on formulary/tier 2 or better)
 Percentage of HMO Lives



Source: Verispan's Managed Care Formulary Drug Audit; Spring 2003; & AHP 339061

⁸⁹ AHP340338

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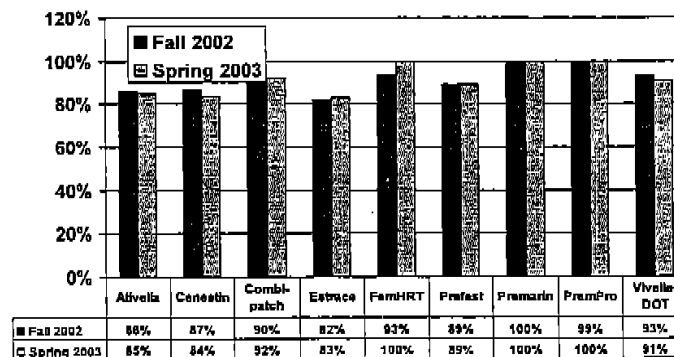
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- **Total Coverage** – “Total Coverage for the Premarin Family remained consistent between the fall 2002 and spring 2003 audit cycles, at virtually 100% for both Premarin and PremPro. Meanwhile, FemHRT increased from 93% to 100% between audit cycles while all remaining HT/ET products stayed relatively consistent in their total coverage of HMO members.”⁹⁰

ET/HT Market

Total Coverage
Percentage of HMO Lives



Source: AHP 340339

⁹⁰ AHP340339

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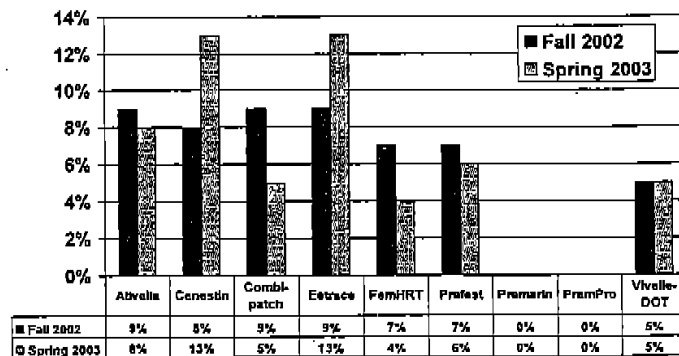
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- **Prior Authorization** – “Overall, the Premarin Family continues to remain unaffected by HMOs’ prior authorization requirements. Additionally, there seems to be a trend in the industry to make more ET/HT products available to the physician and patient. The majority of competing products in the HT/ET market, with the exception of Cenestin and Estrace, experienced a decrease in their prior authorization coverage during the spring 2003 audit cycle.”⁹¹

ET/HT Market Prior Authorization Percentage of HMO Lives



Source: AHP 340340

⁹¹ AHP340339

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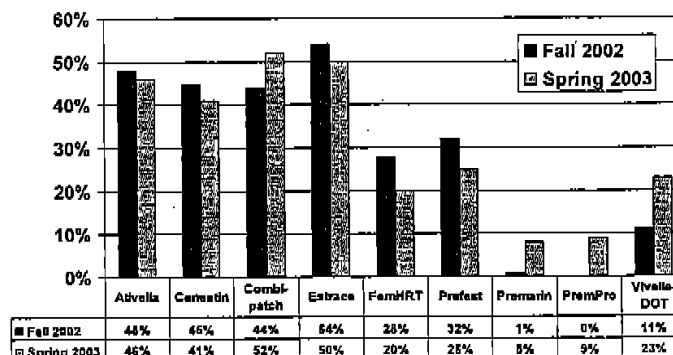
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- **Covered at Third-Tier Co-Pay** – “The Premarin Family experienced an increase in the percentage of lives in third-tier coverage while the competitive HT/ET agents experienced mixed results. Premarin increased from 1% during the fall 2002 to 8% in the spring 2003 audit cycles while Prempro climbed from 0% to 9% during this time period. Meanwhile, FemHRT (28% to 20%) and Prefest (32% to 25%) benefited the most during this time period. Combipatch (44% to 52%) and Vivelle-DOT (11% to 23%), on the other hand, experienced the largest increase in the number of lives falling under third-tier coverage.”⁹²

ET/HT Market Third Tier Coverage Percentage of HMO Lives



Source: AHP 340341

- (WYE 187800) – concerning Aetna's 2001 formulary, “Response was good and eye catching to the physicians to see formulary exclusion of the competitive product Cenestin...”
 - “...competitive ERT/HRT products are hit and miss with coverage on the HMO's in Southern California, therefore use those only for patients who can't take a Premarin Family product.”
 - “Prescribing Premarin, Prempro and Premphase saves time for the office staff and save the patient money leading to less call backs and time spent switching patients.”
 - Premarin, Prempro and Premphase have a \$15.00 co-pay versus Cenestin...which cost the patient a \$30.00 co-pay.”
 - “Lower co-pays for Premarin Family means patients save \$15.00 than using a formulary excluded product.”

⁹² AHP 340340

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- **(WYE 187691)** – "Wyeth and Ayerst reps should be equipped to discuss benefits of formulary products: fewer phone call backs to provider from pharmacy for switches, lower co-pay to patient (there is a \$15 difference between formulary and non-formulary brands."
 - "Reinforce Premarin Family formulary position on other national and local plans and the non-formulary status of ...Cenestin...."
 - "Please make this *'pull through program'* a priority when working with Aetna and field reps during the next few months."
- **(WYE 190646)** – "Although none of the non-formulary products has achieved a large market share, we all know that every Rx they gain is taken from Premarin."
 - "Patients will save money when Premarin products are used. The usual co-pay for our products is \$20 while the usual co-pay for the competitors is \$35. This amounts to a savings of \$180 per year for Premarin (\$15 x 12 months) and \$195 per year for Prempro or Premphase (\$15 x 13 cycles). These co-pays could vary but are correct for the majority of Aetna patients."
 - "Providers will avoid calls from patients and pharmacists to switch to a lower co-pay product if they Rx Premarin family."

Wyeth's use of its market power as an offensive weapon against Cenestin.

Wyeth entered into extensive rebate contracts with every major PBM and MCO to gain formulary position for their Premarin Family of products, most often at the exclusion of their conjugated estrogen competitor, Cenestin.

Wyeth viewed Cenestin as a challenge to their monopolistic position for conjugated estrogen products. One of Wyeth's strategies was called the "Premarkin Preemptive Plan". Webster's dictionary definition of "preempt" is "*to seize upon to the exclusion of others*". Wyeth used previously implemented marketing tactics to seize upon the conjugated estrogen category at the exclusion of Cenestin and thereby continue the company's singular position in the conjugated estrogen ET/HT market.

Wyeth's plan was to protect Premarin's market share and effectively exclude Cenestin from appearing on the formularies of the largest PBMs/HMOs that control the majority of health plan members in the U.S.

Wyeth Rebate requirements and tactics

Well in advance of the launch of Cenestin, Wyeth had developed a variety of types of pricing structures for use in contract generation. These structures supplemented by others described below, constituted the arsenal of contractual weapons subsequently used by Wyeth against Cenestin. The pricing structures were published by Wyeth in a document titled "Contracting Resource Manual" that was published in October 1995.⁹³

⁹³ WYE079940-080095

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Specifically, Section 5 – Proposal Development; Sub-section 5.3 – Types of Pricing Structures⁹⁴ detailed Wyeth's rebate structures that were to be used within all subsequent Reimbursement Agreements with PBMs and MCOs.

Wyeth demonstrated its sophistication in understanding and exploiting the managed care rebate contract environment. The following summarizes the tactics Wyeth incorporated into their rebate negotiating strategy when dealing with MCOs and PBMs.

Wyeth Reimbursement Agreement (Rebate Requirements / Tactics)

The following are examples and not intended to be an exhaustive list of all Wyeth's contracting tactic documents.

1 Premarin was required to be the exclusive or sole conjugated estrogen or preferred estrogen on formulary

WYE 004316 – MedImpact Reimbursement Agreement (4-1-96)

- o Exhibit C, II, A, 1. "Premarkin will be listed in the Formulary and Plan Formulary as the exclusive conjugated Estrogen and the preferred estrogen replacement therapy."

WYE134739 – MedImpact amended agreement (11-14-00)

- o 2.1.3 – "Premarkin shall be listed as the sole conjugated estrogen on the Formulary and Plan Formulary."

WYE124582 – National Prescription Administrators (NPA) Reimbursement Agreement 8-30-00.

- o 2.1.2 – (Formulary Requirements) "Premarkin being listed as the sole conjugated estrogen on the Formulary and Plan Formulary."

WYE010257 – Caremark Reimbursement Agreement 3-23-00

- o 2.1.3 "Products included in the Premarin Family⁹⁵ shall be the sole conjugated estrogen product on the Formulary."

2 All products within a Wyeth "product grouping" must be preferentially listed for any of the group products to be eligible for a rebate

WYE010257 – Caremark Reimbursement Agreement 3-23-00

- o 2.1.1 "In order for any product to be eligible for Rebates, all Products must be included in the Formulary and Plan Formulary."

3 A minimum number of Wyeth's product groupings must appear on formulary to qualify for any rebates

⁹⁴ WYE 079996-080000

⁹⁵ The "Premarkin Family" defined in Schedule A WYE010262

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WYE124016 – Integrated Pharmaceutical Services, Inc. Reimbursement Agreement (7-14-97)

- o II.B "IPS and Type 1 Plans and Type 2 Plans accepting and listing on Core Formulary and Plan Formulary with no prescribing or dispensing restrictions a minimum of seven (7) of the Product Groups listed below according to the criteria listed and Type 3 Plans accepting and listing on the Plan Formulary with no prescribing or dispensing restrictions a minimum of five (5) of the Product Groups listed below according to the criteria listed,.....)

4 Increased rebates are tied to Wyeth products market share increases**WYE124581-82 – NPA Reimbursement Agreement (10-16-00)**

- o Sec 1.16 (standard in most agreements) Relative Market Share Change – formula defined.

WYE124594 – Schedule B: defines rebate by formula**5 Rebates are tied to Cenestin market share decreases****WYE012690-91 – Merck-Medco Managed Care Amendment to the 01-01-00 agreement dated 08-16-00.**

- o "The following shall be added to the end of Part A, Section III: L. Wyeth-Ayerst shall pay an additional Premarin/Prempro/Premphase Market Share Rebate to Medco each Contract Quarter in an amount equal to 0.75% of the Medco mail service volume of Premarin/Prempro/Premphase for each contract Quarter for each 10% or portion thereof that the Medco Mail Service Market Share of Cenestin....is below the National Market Share of such Products..."

6 Available rebate percentages increase as additional Wyeth products are included on formulary – incentive rebates**WYE010345 – Advance Paradigm Clinical Services, Inc. Reimbursement Agreement 05-07-97**

- o Schedule C1 All oral estrogens and estrogen/progestin combination (Premarin/Prempro/Premphase)

WYE010346 – Schedule C2 Product Performance Rebates defined by performance above baseline.**WYE124019 – IPS Reimbursement Agreement, 07-14-97**

- o "Type 2 Plans or Type 3 Plans/Groups of Plans that elect collectively to accept seven (7) or more of five (5) or more...."

WYE009111 – Aetna Health Management Reimbursement Agreement, 07-17-97

- o II, A, 1 – Product Groups: HRT Products, "Premarin, Prempro and Premphase must be listed on the Voluntary Formulary and the Select Formulary as the sole conjugated estrogen-containing products, and a preferred hormone replacement product."

WYE009115 –

- o Sec III, graph on group incentives

7 NDC blocks, to lock out competitors' products from the formulary, may be required

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WYE023418 – Wellpoint Pharmacy Management, Reimbursement Agreement Amendment to the contract; 09-29-00.

- o Point 4: Exhibit C. Section II.B.1.

8 Additional monies paid as “Admin. Fees” and/or “Service Fees” by Wyeth to client for client services rendered to Wyeth

WYE124584 – NPA Reimbursement Agreement (10-16-00) “service fee”

- o Sec 3.5, “Wyeth-Ayerst shall pay a 2% *Service Fee* on the Net Sales...”
- o 3.51-.58, “PBMs providing services to Wyeth-Ayerst that will include, but not necessarily be limited to the following:”

WYE010956 – “Products specifically excluded from Rebates and Administrative fees” (see Exhibit D below⁹⁶).

WYE010967 – administration fee described in Exhibit D

9 Specific formulary promotional efforts are required of some clients

WYE006084 – Medco Pharmaceutical Supply Agreement, 10-01-95

- o 6.1.1. “...Physicians representing a minimum of ninety (90%) percent of prescriptions written for competing branded oral estrogens dispensed at retail...”

10 Wyeth may apply formulary promotional efforts to some client physicians and pharmacies

WYE124016 – IPS Reimbursement Agreement, 07-01-97.

- o II.B.1.HRT Products

11 Pharmacies must dispense as written, without changing to a competing product

WYE124017 –

- o II.C “...No Pharmacy initiated program involving product interchange...”

12 Wyeth leveraging their position threatening loss of rebates if competing products are put on formulary

WYE157987 - 990 – Rocky Mountain HMO letters

WYE117064 – 1. Key Issue, “...Express Scripts accepted Cenestin as part of their Bid Grid. Upon our objection, they notified Duramed that they would NOT accept a contract on the product.”

Wyeth viewed Cenestin as a “significant challenge” to their women’s health care single source and exclusive franchise

- Wyeth document #**WYE118176**, an internal Wyeth memo, dated March 26, 1999 states:

⁹⁶ WYE010967

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- o "The approval of Cenestin is a *significant challenge* to our women's health care franchise..."
- o "...we must reinforce those managed care contractual arrangements that identify Premarin as the exclusive conjugated estrogen on formulary."
- o "I ask that you communicate any account issues or challenges related to Cenestin immediately. Executive management has requested regular updates from all field personnel."

Wyeth developed a sophisticated offensive marketing strategy known as the "Premarkin Preemptive Plan"⁹⁷ to attack Cenestin as it was introduced into the market.

The "Premarkin Preemptive Plan" was sophisticated marketing strategies presented in 1999 to target and inhibit Cenestin's market entrance. The overall goal of the plan was to hold Cenestin to less than 2% TRx share in 1999 (approximately \$20 million).⁹⁸

The plan asserted that a number of clinically relevant attributes made Premarin superior to any other conjugated estrogen on the market, including Cenestin.

- The plan called for selling the "science of Premarin."⁹⁹
- A format for developing a detailed "Cost Analysis" for each MCO and PBM was developed.¹⁰⁰ This analysis demonstrated both the value of the Wyeth rebate package and the downside risk of losing the rebates if Cenestin were permitted onto the Formulary.
- The plan called for a "Medical Affairs Response Team"¹⁰¹ consisting of physician speakers with regional and national reputations; and a "Clinical Consultant Bureau"¹⁰² that consisted of Pharm.D. speakers from academic backgrounds that would be available to address physician meetings and present the above messages ("science of Premarin") to professional audiences.
- In addition the plan called for "blast faxing" press releases & short Q & As to external spokesperson advocates.¹⁰³
- The plan called for the cultivation of alliances with key medical and pharmaceutical professional and trade associations along with patient advocacy groups.¹⁰⁴
- Full page ads were to be placed in various national publications (*USA Today*, *the Washington Post*) to articulate the above message.¹⁰⁵

⁹⁷ WYE132250 - 132311

⁹⁸ WYE132253

⁹⁹ WYE132290-91

¹⁰⁰ WYE132293

¹⁰¹ WYE132273

¹⁰² WYE132275

¹⁰³ WYE132305

¹⁰⁴ WYE132303

¹⁰⁵ WYE132307

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- There was an integrated time line published that coordinated the components of the plan leading up to and following the anticipated market entrance of Cenestin in April of 1999.¹⁰⁶

Negotiated and enforced market share agreements to protect its single source status

Wyeth's existing rebate contracts with the largest PBMs/MCOs required that Premarin be either the *sole* conjugated estrogen on their formularies or the preferred drug in the oral estrogen category. Wyeth considered it a breach of their rebate contract by the PBMs/MCOs if they were to allow Cenestin on their formularies or allowed it to be classified as anything but non-preferred. Such a breach could lead to the loss of *all* rebates for *all* Wyeth products. Wyeth enforced their contracts to prevent Cenestin from appearing on the formularies where it enjoyed a sole conjugated estrogen status.

- Wyeth document #WYE118139, an attachment to an internal Wyeth memo, dated March 9, 1999 illustrates Wyeth's dominant formulary position with PBMs & HMOs:
 - Wyeth had either an exclusive or a preferred formulary status with all the large underwriters and PBMs in the market with the single exception of Humana (Caremark is classified as N/A).

Account	# Lives (Members)	W-A Contract Status
Low Control		
Caremark	8.4	N/A
Express Scripts/Value Rx	21.7	A
MEDCO	52.0	A/B
MedImpact	3.4	A/B
NPA	7.5	A
PCS	56.0	B
ProVantage	3.8	A/B
Prime Therapeutics	5.0	B
Subtotal:	157.8	
Medium Control		
Aetna (w/Prudential)	13.4	A/B
API	12.5	A/B
Coventry	1.5	B
DPS	20.2	B
Humana	6.2	C
Wellpoint	8.6	A/B
Subtotal:	62.4	
High Control		
CIGNA	6.4	B

¹⁰⁶ "Cenestin Plan Implementation"; WYE132279

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Foundation (IPS)	15.5	A
Kaiser	8.1	B
Pacificare	4.5	A
Subtotal:	34.5	

TOTAL:	254.7
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Source: #WYE118139

* A = Exclusive Conjugated Estrogen

B = Preferred Oral Estrogen

C = Non-preferred Status

Wyeth enforced the terms of their contracts

- Wyeth document **WYE117064** Sec. 1, an internal Wyeth memo regarding Wyeth's formulary relationship with Express Scripts, ValueRx/DPS dated Nov. 4, 1999, states:
 - "Express Scripts accepted Cenestin as part of their Bid Grid. Upon our objection, they notified Duramed that they would NOT accept a contract on the product."
- Wyeth document **WYE025546**, an internal Wyeth memo, dated Nov. 9, 1999, states:
 - "A signed agreement with Duramed, which had added Cenestin to the Express Scripts formulary, was reversed by quick, concerted action between national account sales and CD&A. To date, no known managed care accounts have Cenestin on formulary."
- Wyeth document **WYE051073**, Wyeth's "Managed Care National Accounts Action Steps", instructs Wyeth employees:
 - "-Continue to position Premarin Family as preferred ERT/HRT agents at each National Account
 - Ongoing evaluation of each National Account relative to performance and rebates
 - "Enforce terms of contract"

Wyeth threatened MCOs with loss of their rebate income

Wyeth communicated to their clients that a breach of their rebate contract would result in Wyeth not paying rebates on Premarin and /or all Wyeth products.

- WYE023598-600**, an internal memorandum from Sally Miller detailing the contents of a meeting with Jim Hill at ExpressScripts: "First on the list was Premarin. He (Hill) started out by saying that they had a small but persistent group of clients who were insisting on having Cenestin available and he "needed" to renegotiate the contract. I replied that under no circumstances would we agree to do this and reminded him that they (ExpressScripts) are receiving over \$40 million in rebates per year that would be at risk..."
- Wyeth document **WYE157990**, an October 6, 1999 letter from Wyeth-Ayerst to Rocky Mountain HMO states:

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- "According to the terms of the MedImpact Agreement, should Rocky Mountain HMO add Cenestin™ to its formulary or take any action against our oral contraceptives, we will exercise the thirty (30) day no cause termination option in the agreement, and inform MedImpact that Rocky Mountain HMO is no longer eligible to participate in the MedImpact/Wyeth-Ayerst Reimbursement Agreement."
- Wyeth document **WYE157987-988**, An Dec. 14th, 1999 letter from Rocky Mountain Health Maintenance Organization to Wyeth-Ayerst states:
 - "RMHMO is seriously concerned about the statements made in your letter regarding Wyeth-Ayerst exercising a 30-day no cause termination option if RMHMO adds Cenestin™ to its formulary or takes 'other action' against Wyeth-Ayerst oral contraceptives. We are all well aware of the large market share Wyeth-Ayerst has with its Premarin Family in that category of pharmaceuticals. We seriously question the appropriateness and legality of Wyeth's attempt to use such market share to influence RMHMO's decisions with regard to its formulary for other pharmaceutical products."

Wyeth used their market position to negotiate exclusive contracts

Wyeth's rebate contracts provided significant rebate dollars for the PBMs/HMOs if they protected Premarin's market share from competition like Cenestin. Wyeth leveraged their exclusive contracts and rebate dollars with the PBMs/HMOs to keep Cenestin off their formularies.

- Wyeth document **WYE118068**, an internal Wyeth memo about a phone call with Advance Paradigm, dated Feb. 19, 1999 states:
 - "Our position is protected with API (Advance Paradigm, Inc.) as far as our contractual language regarding Premarin. It reads as follows: 'Pemarlin, Prempro and Premphase ("Pemarlin Products") must be listed on the Formulary and Plan Formulary as the sole conjugated estrogen-containing products."
- Wyeth document **WYE118069**, an internal Wyeth memo with the subject heading of "Likelihood of Cenestin added to Plan Formularies", dated Feb. 24, 1999 states:
 - "Charles-Per your voicemail as far as determining the estimate of plans that will add Cenestin to formularies, the decision will be solely dictated by how Duramed's product will be classified."
 - "If the product is classified as a conjugated estrogen we are protected by contractual language for API (Advance Paradigm, Inc.) and NPA (National Prescription Administrators) therefore the percentage will be 0% for both."
- Wyeth document **WYE117253**, an internal Wyeth memo about a meeting between Wyeth and Medco, dated May 10, 1999 states:
 - "The purpose of this meeting was to evaluate current programs and to discuss tentative plans for moving forward. Each party came to the meeting with their list of needs. Objectives I established for this meeting included; (1) *Gain commitment to make Cenestin "non-formulary drug" as per contract Premarin is the "exclusive conjugated estrogen on formulary and the preferred oral estrogen therapy."*

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- "After reviewing our contractual arrangement for Premarin, Art agreed that Premarin is the sole conjugated estrogen per terms of the contract. Art will talk with Glen Taylor to determine if "prior authorization" can be put in place for Cenestin."
- Wyeth document **WYE118196**, a memo from Wyeth to Wellpoint dated April 6, 1999 conveying Wyeth's Cenestin Impact Model to WellPoint, as well as reminding WellPoint of their exclusive agreement for Premarin:
 - "For your consideration, our contract dated October 1, 1996, includes language which pertains to this issue. Page 10, Section HB I states 'Premarkin, Prempro and Premphase must be listed on the Formulary and Plan Formulary as the *sole conjugated estrogen-containing products*...."

Wyeth worked with PBMs / MCOs to exclude Cenestin from their formularies

- Wyeth document **WYE118068**, an internal Wyeth memo about a phone call with Advance Paradigm, dated Feb. 19, 1999 states:
 - "Karl wants to identify partnering strategies and tactics on how we can together with API blunt the launch of Cenestin. He spoke of mailings, programs etc. that API would be willing to work with W-A to target the current Premarin users as well as target new Rx's."
- Wyeth document **WYE118389**, an internal Wyeth document referencing discussions with IPS, dated April 11, 1999, states:
 - "I will be meeting with the account on 4/19 and will discuss the status of 4Q98 rebates as well as the contractual language which prohibits any other conjugated estrogen from formulary status.
 - I have spoken to Gina Warren, Pharm D., at IPS, who is preparing a monograph on Cenestin and she is aware of the contractual prohibition.
 - I have asked all other AAMs to meet with their FHS contacts and reinforce the contractual language with the (client)
 - I am confident, IPS and FHS will comply with the contract and *Cenestin will remain non-formulary*. Adjustments on rebates would be an additional enhancement to their contractual compliance."
- Wyeth document **WYE117146**, an internal Wyeth memo regarding Foundation Health Plan, dated May 4, 1999, states: "Key Issues:
 - "Value' of Premarin contract in face of Cenestin and decreasing market share in key accounts."
 - "Contracting language prohibiting any other conjugated estrogen needs to be communicated to all plans."

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The Managed Care Cost Analysis

Wyeth devised a strategy whereby they could either reward or punish an MCO if it did or did not permit Cenestin to have access to the MCO's formulary.¹⁰⁷

The Cenestin Impact Model clearly illustrated to the PBMs/HMOs the loss of Wyeth rebate dollars that would occur if they placed Cenestin on their formularies with a resulting loss of market share for Premarin. Not only did Wyeth demonstrate loss of rebate dollars for their Premarin product, the Cenestin Impact Model communicated a potential total loss of rebate dollars for all Wyeth products, which would result from allowing Cenestin on their formularies.

- Wyeth document **WYE118080-8105**, an internal Wyeth memo dated March 8, 1999 illustrated the fact that the Cenestin Impact Model went out to all of Wyeth's National Account Managers:

"The attached Excel files include directions for use, key assumptions, summary, and detail sheets pertaining to all national accounts. Please be advised that each National Account Manager has been mailed a similar account specific file."

Demonstrating the Managed Care Cost Analysis required constructing an existing market snapshot. This demonstration combined market share penetration for Wyeth products and quantifying the rebates that were being paid to the MCO prior to the market introduction of Cenestin.

The following example of a Managed Care Cost Analysis uses the Pacificare account.¹⁰⁸ Pacificare had 4.5 million members at the time of this analysis. As one of Wyeth-Ayerst major national accounts, Pacificare received \$3.8 million in rebates from the Premarin family of drugs and \$3.3 million in rebates from all other Wyeth-Ayerst products.

Pacificare Market Cost Analysis¹⁰⁹

	Market Share		Annualized		
	National	Account	AWP Gross Sales	Rebates	AWP Net Sales
Premarin Total	74.4%	77.8%	\$ 28,550,325	\$ 3,839,390	\$ 24,710,935
<i>Tabs</i>	54.5%	62.1%	\$ 21,114,020	\$ 2,824,570	\$ 18,289,450
<i>Prempro/Phase¹</i>	19.9%	15.6%	\$ 7,436,305	\$ 1,014,820	\$ 6,421,485
OCs	23.3%	21.2%	\$ 6,348,650	\$ 2,654,676	\$ 3,693,974
Effexor ²	7.1%	6.4%	\$ 4,087,478	\$ 326,883	\$ 3,760,594
All other Products			\$ 2,138,190	\$ 300,664	\$ 1,837,526
			\$ 41,124,643	\$ 7,121,613	\$ 34,003,029

¹ PREMPRO therapy consists of a single tablet containing 0.625mg of the conjugated estrogens found in PremarinTM tablets and 2.5 mg or 5 mg of medroxyprogesterone acetate (MPA) for oral administration.

² A structurally novel antidepressant for oral administration. It is chemically unrelated to tricyclic, tetracyclic, or other available antidepressant agents.

¹⁰⁷ WYE117988, WYE117989

¹⁰⁸ It should be noted that while this example summarizes a set of hypothetical scenarios for Pacificare, similar financial projections were prepared for each of Wyeth's MCO and PBM accounts.

¹⁰⁹ WYE118080-118105

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Wyeth-Ayerst account reps would then demonstrate what would occur if Cenestin were permitted, through formulary inclusion and tiered structure placement, to erode Premarin's market share position. The following table assumes a 5% shift in Premarin's existing conjugated market share to Cenestin. Such a change would require an 8% shift of 0.625 mg tablet business.

Assumes a 5% shift in Pacificare's Premarin market share.

	Market Share		Annualized		
	National	Account	AWP Gross Sales	Rebates	AWP Net Sales
Premarin Total	74.4%	74.6%	\$ 27,494,624	\$ -	\$ 27,494,624
<i>Tab</i> s	54.5%	59.0%	\$ 20,058,319	\$ -	\$ 20,058,319
<i>Prempro/Phase</i>	19.9%	15.6%	\$ 7,436,305	\$ -	\$ 7,436,305
Cenestin**	0.0%	3.1%	\$ 950,131	\$ -	\$ 950,131
OCs	23.3%	21.2%	\$ 6,348,650	\$ 2,654,676	\$ 3,693,974
Effexor	7.1%	6.4%	\$ 4,087,478	\$ 326,883	\$ 3,760,594
All other Products			\$ 2,138,190	\$ 300,664	\$ 1,837,526
			\$ 41,019,073	\$ 3,282,223	\$ 37,736,849
			Cost/(Savings) @ AWP	Gain/(loss) in rebates	Cost/(savings) Net to Acct. @ AWP
			\$ (105,570)	\$(3,839,390)	\$ 3,733,820

**Model assumes no rebate and no discount off AWP for acquisition

There are several messages that Wyeth sought to communicate to the pharmacy director at Pacificare within this demonstration. These include:

1. Based upon Wyeth's projected AWP for Cenestin, overall cost savings to Pacificare by moving 5% of the conjugated market to the less expensive Cenestin would generate only \$105,570 in AWP savings.
2. On the other hand, should Premarin's market share deteriorate, even by 5%, the entire rebate for the Premarin family of drugs will go away – this represents a loss to Pacificare of \$3,839,390 annually.
3. The discounts from AWP for acquisition costs will no longer apply. Thus increasing acquisition costs by \$3,733,820.¹¹⁰

To leave no doubt in the mind of the pharmacy director at Pacificare, Wyeth's field representatives presented the director with the consequences of Premarin experiencing a 5% shift in conjugated market share to Cenestin AND cancellation of Wyeth's contract.

¹¹⁰ The model should have raised questions in the pharmacy director's mind in that the model assumes no rebates or discount off AWP for acquisition of Cenestin.

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Assumes a 5% shift in Pacificare's Premarin market share AND cancellation of the entire Wyeth rebate and AWP discounted acquisition contract.

	Market Share		Annualized		
	National	Account	AWP Gross Sales	Rebates	AWP Net Sales
Premarin Total	74.4%	74.6%	\$ 27,494,624	\$ -	\$ 27,494,624
<i>Tabs</i>	54.5%	59.0%	\$ 20,058,319	\$ -	\$ 20,058,319
<i>Prempro/Phase</i>	19.9%	15.6%	\$ 7,436,305	\$ -	\$ 7,436,305
Cenestin*	0.0%	3.1%	\$ 950,131	\$ -	\$ 950,131
OCs**	23.3%	21.2%	\$ 6,348,650	\$ -	\$ 6,348,650
Effexor**	7.1%	6.4%	\$ 4,087,478	\$ -	\$ 4,087,478
All other Products**			\$ 2,138,190	\$ -	\$ 2,138,190
TOTALS			\$ 41,019,073	\$ -	\$ 41,019,073
			Cost/(Savings) @ AWP	Gain/(loss) in rebates	Cost/(savings) Net to Acct. @ AWP
			\$ (105,570)	\$ (7,121,613)	\$ 7,016,044
* Model assumes no rebate and no discount off AWP for acquisition					
** Assumes loss of AWP% discount on product acquisition					

The following set of tables illustrates the fact that with further deterioration in Premarin's market share, the consequences to Pacificare will become even more catastrophic. This model assumes that there will be a 63% shift in conjugated market share to Cenestin within the Pacificare account. This will require a Premarin loss of 100% of the 0.625 mg dosage market.

Assumes a 63% shift in conjugated market share to Cenestin and cancellation of the Wyeth-Ayerst AWP discounted contract.

	Market Share		Annualized		
	National	Account	AWP Gross Sales	Rebates	AWP Net Sales
Premarin Total	74.4%	38.6%	\$ 15,248,492	\$ -	\$ 15,248,492
<i>Tabs</i>	54.5%	23.0%	\$ 7,812,187	\$ -	\$ 7,812,187
<i>Prempro/Phase</i>	19.9%	15.6%	\$ 7,436,305	\$ -	\$ 7,436,305
Cenestin**	0.0%	39.1%	\$ 11,971,649	\$ -	\$ 11,971,649
OCs	23.3%	21.2%	\$ 6,348,650	\$ 2,654,676	\$ 3,693,974
Effexor	7.1%	6.4%	\$ 4,087,478	\$ 326,883	\$ 3,760,594
All other Products			\$ 2,138,190	\$ 300,664	\$ 1,837,526
			\$ 39,794,459	\$ 3,282,223	\$ 36,512,235
			Cost/(Savings) @ AWP	Gain/(loss) in rebates	Cost/(savings) Net to Acct. @ AWP
			\$ (1,330,184)	\$ (3,839,390)	\$ 2,509,206

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Wyeth enhanced their contract terms with certain accounts to protect their existing exclusive formulary position

In some instances, where Wyeth felt Premarin's exclusive formulary position was at risk with a PBM/HMO client, Wyeth revised their agreement to increase the rebate dollars paid to the client and lowered the market share performance requirement for their client to achieve the increased rebate amounts and paid retroactive rebates.

- Wyeth document **WYE118320**, an internal Wyeth memo dated February 24, 1999, indicates:
 - "At our Fast Start meeting in Dallas Bob Repella stated the importance of us being able to amend our national account contracts so our clients' Premarin performance parameters would be adjusted according to changes in the National Premarin performance. We had discussed trying to make this offer not appear as a defense strategy to the market entry of Cenestin – which will require that we do something quickly"
- Wyeth document **WYE154418**, an internal Wyeth memo discussing rebate strategy for IPS, indicates:
 - "If we can adjust the Baseline on a quarterly basis we will have an incentive for IPS and the plans to NDC block Cenestin and where necessary place the product in the highest co-pay category..."
- Wyeth document **WYE117191**, an Internal Wyeth memo dated February 28, 1999, indicates "February Highlights":
 - "Review Premarin baseline level for Key FHS plans and determine best strategy for preserving value"
- Wyeth document **WYE118389**, an internal Wyeth memo dated April 11, 1999, regarding IPS rebates, indicates:
 - "Adjustments on rebates would be an additional enhancement to their contractual compliance"
- Wyeth documents **WYE000036 & WYE000037**, an internal Wyeth memo with "Pricing Committee Meeting notes of Oct. 27, 1998" regarding Aetna/US Healthcare indicates:
 - "Reestablish the Premarin Family rebates schedule, which was applicable in 1997 with some revision..."
 - "In turn for the concessions Aetna would:
 - Assure that the Premarin Family products are the sole multi-estrogen component EHT/HRT products listed in the formulary."
- Wyeth document **WYE032576**, an internal Wyeth memo undated, states:
 - "Charles explained to the Pricing Committee in 1997 Aetna received rebates for Premarin @ 3%. With the signing of the new contract, Wyeth-Ayerst took those rebates away. Charles proposed if Aetna agrees to include additional language regarding blockage of Cenestin, then Wyeth should in turn reinstate the 3%

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Premarin rebates. The addition of this language should/could help/maintain our current market share. This was approved by the Pricing Committee."

- Wyeth document **WYE032575**, an internal Wyeth memo dated July 1, 1999, states:
 - "We just had a meeting with regards to Aetna's fourth quarter 1998 payment. The dollar increase with the new amendment comes in around \$800,000."
- Duramed document **DUR010786**, a Viking Managed Care Update submitted 11/99, states:
 - "I did speak with Dan concerning Caremark's decision regarding Cenestin and/or Premarin before he left 11/12/99. Based on Wyeth's last proposal it appears that they will go with Premarin. Dan said that the contract would net Caremark more than \$1,000,000 in profits annually."
- Wyeth document **WYE049692**, an internal Wyeth memo dated April 13, 1999, indicates about ProVantage:
 - "The ProVantage Reimbursement Agreement Amendment has been signed and forwarded to Lois Rulli. The effect of the amendment is to roll back the Premarin, Prempro and Premphase baseline rebate level to what it was at the beginning of the contract. It is effective as of 3Q98. Please ask Lois for a copy of the amendment and then you can process the submission you have in house – they should earn Premarin rebates as a result of the amendment."

The effect formulary exclusion of Cenestin had on physicians

The importance of formulary inclusion and positioning is well documented within the papers filed in this case. I cite the following as examples:

- **(CM:00513)** – "HMOs (Independent Health) continue to reject scripts written for Cenestin, even when the doctor fills out a prior authorization. Physicians are therefore reluctant to write any more scripts for Cenestin."
- **(CM:00525)** – "...physicians describe how FL Managed care plans are rejecting Cenestin Rx's. (The physicians) are frustrated."
- **(CM:00523)** – "...two physicians wrote scripts for Cenestin. However, due to formulary constraints, the scripts were filled by Premarin."
- **(CM:02691)** – "Dr. Morris Elstein in Virginia Beach indicated to me that he likes Prometrium (progesterone, USP) very much and would like to write Cenestin. However, he says that CIGNA does not have Cenestin on their formulary, therefore it is too expensive for many of his patients who are military, who can get Premarin at the base for next to nothing."
- **(CM:00501)** – "once a physician's Rx is rejected at the drug store, that physician is VERY reluctant to Rx (Cenestin) again."
- **(CM:00519)** – Dr. Montsemat has been receiving phone calls from pharmacies asking if they can switch Cenestin to Premarin. The reason they say is because the insurance is rejecting the claim."
- **(CM:00505)** – "...a large OB/GYN office will only Rx when the rep. produces a list of guaranteed approved formularies."

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- **(CM:00497)** – "I am not going to write Cenestin till it's on the formulary."
- **(CM:00503)** – "90% of my patients are on formularies and I won't prescribe it unless it's on the formularies."
- **(CM:00509)** – "Doctors continue to be frustrated by writing Rx's for Cenestin only to have them rejected and redirected to another brand because of lack of formulary approval...It is not the product (Cenestin) the doc's are concerned with, it's the formulary status. They do not want to deal with the calls from pharmacists and additional paper work."
- **(CM:00510)** – "Time and again, doctors Rx Cenestin only to have it rejected. It won't be too long before they won't write it period."
- **(CM: 02640)** – "Dr. Minton (Fort Worth, TX) had had 24 prescriptions rejected at the pharmacy level. His nurse was quite frustrated naturally..."

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Signature Page



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David J.
Gibson

Digitally signed by David J. Gibson
DN: CN = David J. Gibson, C = US
Reason: I am the author of this
document
Date: 2004.04.22 09:01:17 -07'00'

April 22, 2004

Date

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Attachment A: Curriculum Vitae

David J. Gibson, M.D.

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Carmichael, CA 95608
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916.359.4267 fax
davidjgibson@msn.com

Experience

The Fraud Prevention Institute (FPI)

Chief Executive Officer
2003 - Present

The Fraud Prevention Institute (FPI) is a California based non-profit organization. FPI is a business league whose purpose is to promote the common business interests of health care providers by preventing, detecting and eradicating fraud in the health care industry. To accomplish this mission, FPI conducts active programs of research, education, consulting, and network management. All of these activities are aimed at elevating ethical standards of health care providers and eliminating fraud in the industry.

FPI's technology was developed by a joint task force consisting of the Federal Bureau of Investigation and the Medi-Cal Fraud Prevention Bureau. This task force has investigated more than 500 Medi-Cal providers over the last few years. These investigations produced a 100% conviction rate. The task force charged 314 individuals with \$200,000,000 fraud. To this date, 195 have been convicted with \$72,000,000 restitution recovered. The senior agents, both state and FBI have joined FPI on a full time basis and make up the operational core of the organization.

Illumination Medical Inc.

Partner & Chief Operating Officer
2003 - Present

Illumination Medical is a unique, specialty consulting organization. Large managed care underwriting companies tend to focus their resources upon their fully insured products that are defined by state insurance law. Furthermore they tend to bring this orientation to their administrative services only (ASO) contracts. This is certainly the case for organizations like Blue Cross across the country.

ERISA and Taft-Hartley Trusts need consulting support that focuses upon the Trust's unique position within the market and leverages the Trust's advantages under Federal Law. Illumination Medical, Inc. targets its services to serve mid sized self funded trusts including ERISA and Taft-Hartley trusts.

Illumination Medical's core competency centers upon evolving problems faced by *all* health plans. Actuarial support, administrator and PBM auditing, and traditional claims

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based benefit design activities are all still important but no longer fully meet the evolving needs of health plans in today's market. It is now incumbent upon health plan administrators to manage proactively using current data rather than reactively using past experience.

Pharmaceutical Care Network (PCN)

Medical Director

2002 – Present

Based in Sacramento, California, PCN is a full service pharmacy benefit management and healthcare information management company providing services to Medicaid Managed Care Plans, self-funded employer groups, Health & Welfare Trust Funds, Third Party Administrators, HMOs and other Managed Care Organizations. MedIntelligence, the clinical offering from PCN, provides healthcare information management services to the health care industry, and focuses on improving outcomes - both clinical and financial. PCN's mission is to maximize the value of health care by managing pharmaceutical information, programs and services for its customers. I serve as the Chairman of the Pharmacy and Therapeutics Committee for PCN and have responsibility for developing the company's formulary. I also serve as the Chairman of the Quality Assurance activities for PCN functioning as a delegated manager for a number of NCQA qualified MCOs.

The Pacific Development Group

President

2000 - Present

Founded a consulting group that consists of health care executives with extensive experience in developing and managing physician organizations. The group is recognized for its intimate knowledge of healthcare markets throughout the United States. In addition, the group is known nationally for its experienced leadership of pharmacy networks. PDG's focus is the development and deployment of physician connectivity modalities throughout the West Coast, Hawaii as well as other markets. Furthermore, PDG will exploit the business opportunities that result from a long-term relationship with the prescribing physician or medical group using these evolving information technologies.

RxPhysician.com

Chief Executive Officer

1998 - 2001

Founded a medical information integration company specializing in pharmacy ordering systems. The Company utilizes innovative hand-held wireless technology to permit the prescribing physician to have full access to computer databases from the mobile pocket in his lab jacket. The Company has deployed its systems at the Santa Barbara Medical Foundation in Santa Barbara, CA and at the Straub Clinic and Hospital in Honolulu, HI.

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CASIO Manufacturing Corporation

Chief Medical Officer – American Research and Development
1999-2001

Provided technical assistance to the Research and Development Group, which is based in San Jose California. Primary area of interest involved business-to-business (B-2-B) applicability of CASIO's hand-held technology with wireless linkage to the Internet.

Longs Drug Stores and RxAmerica

Chief Medical Consultant
1998 - 2001

Provided consulting services to Longs Drug Stores, with sales averaging over \$8.7 million per store, Longs operates 460 stores and is the largest drug store chain in Hawaii. With 400 clients and 3.1 million lives represented, RxAmerica is a leading provider of Pharmacy Benefits Management (PBM) Services. My responsibility was to provide consultative services to both organizations. I focused my attention on the development of a stronger professional relationship between the dispensing pharmacist and the prescribing physician. Specifically, I developed a series of B-2-B tools to facilitate the strengthening of the professional relationship using the Internet as the method of communication.

Omni HealthCare

Vice President, Medical Affairs & Chief Medical Officer – Insurance Products, the Sutter System
1996 – 1998

Responsible for medical related policy and operational issues. Omni HealthCare was a 175,798 member, California based, for profit health plan, owned by the Sutter/CHS Health System. Omni's annual revenue stood at over \$157 million. The provider network consisted of 1,000 primary care physicians, 2,400 specialists, and 50 hospitals.

Medical Technology Transfer Corporation

President
1994 -1996

I started the company and sold a major equity position. The Medical Technology Transfer Corporation (MTT Corp) is an investment and management company. It develops advanced imaging centers throughout the world and tele-communicates the digital data via satellite and fiber optic landlines back to the faculty practice at leading academic medical centers in the United States. MTT Corp leads a consortium of companies including Semen's Medical Systems, Harris Corporation and UCLA in its imaging center development activity. Projects included a facility in Melbourne, Florida; Buenos Aires, Argentina; Santiago, Chile and Costa Rica.

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UCLA Medical Group Practice

Chief Executive Officer
1993-1994

The UCLA Medical Group Practice is the second largest group practice in the United States encompassing over 800 physicians. The group consisted of the full and part time faculty members in the UCLA School of Medicine.

Metropolitan Life Insurance Company (MetLife)

Vice President for Medical Affairs & CMO - Florida
1991-1993

Supervised medical benefits administration for over 935,000 insured. The total dollars managed exceeded \$1.12 billion annually and represented 14 percent of MetLife's total managed indemnity and 7 percent of its total HMO book of business. The Florida network for MetLife consisted of thirty-eight hundred physicians and twenty-three hospitals.

Avanti Health Systems

President and Chief Executive Officer
1984 - 1991

Avanti Health Systems was a development and management firm. Projects developed were national in scope with locations in Texas, Florida, Colorado, California, Connecticut and other states. When operational, the independent managed care companies developed grossed over \$150 million in 1987. Their gross revenues in 1988 exceeded \$250 million. Most of these managed care companies have been acquired by national insurance companies during the early 1990s.

Santa Barbara Medical Foundation Clinic

Partner
1977 - 1984

Clinical practice of Rheumatology within the Department of Medicine. Academic appointments at both UCLA and the University of Southern California (U.S.C.). I also served as President of the Santa Barbara Society of Internal Medicine.

Education

Asbury College

B.A., Liberal Arts, 1967

University of Kentucky

M.D., 1971

University of Indiana

Internship and Residency in Internal Medicine, 1973

Harvard University

Research Fellow - Rheumatology, 1975

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Academic Appointments

Harvard University

*National Institutes of Health Research Fellow
Clinical Proctor, Internal Medicine*

Louisiana State University School of Medicine (LSU)

Clinical Associate Professor of Medicine - Rheumatology

University of California Los Angeles School of Medicine

Clinical Associate Professor of Medicine - Rheumatology

University of Southern California School of Medicine

Clinical Associate Professor of Medicine - Rheumatology

University of Texas Medical School - Houston

Clinical Associate Professor of Medicine - Rheumatology

Licensure

California # G33504

Certification

National Board of Medical Examiners #118712
The American Board of Internal Medicine #47482

Personal Data

- Associate editor of *SSVMedicine*, the official publication of the Sierra Sacramento Valley Medical Society (SSVMS) - <http://www.ssvms.org/magazine.asp>
- Member of the Medical Practices Committee for the California Medical Association (CMA).

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Attachment B: Bibliography

**Articles written during the last 10 Years by
David J. Gibson, M.D.**

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Bibliography: SSV Medicine

The Sierra Sacramento Valley Medical Society

David J. Gibson, MD



All articles are hyperlinked to:
<http://www.ssvms.org/index.asp>

SSVMS: Sierra Sacramento Valley Medicine - Vol. 52 / No. 5 - Sep / Oct 2001

Spending More on Drugs, by David J. Gibson, MD - The United States should - and inevitably will - be paying at least twice as much for drugs. The bad news is the likely source of those dollars.

SSVMS: Sierra Sacramento Valley Medicine - Vol. 52 / No. 6 - Nov / Dec 2001

Our Pursuit of Mediocrity, by David J. Gibson, MD - Why does California want a Third World health care system?

SSVMS: Sierra Sacramento Valley Medicine - Vol. 53 / No. 1 - Jan / Feb 2002

My Experience with Health Care Inflation in the ER, by David J. Gibson, MD - Physicians need to do something about the high cost of ambulatory care in the hospital setting - because they'll be blamed for the mess in any event.

SSVMS: Sierra Sacramento Valley Medicine - Vol. 53 / No. 2 - Mar / Apr 2002

"John Q" is Worth Seeing, by David J. Gibson, MD - Denzel Washington's new movie, "John Q," is worth watching. It will likely become part of the public discourse on where we go with health care in the future.

SSVMS: Sierra Sacramento Valley Medicine - Vol. 53 / No. 2 - Mar / Apr 2002

Morphing of Health Care, by David J. Gibson, MD - Financing of health care in the United States is now entering a period of rapid change. For the past 15 years, managed care has been the predominant product that employers have selected to manage the group health benefit for their employees.

SSVMS: Sierra Sacramento Valley Medicine - Vol. 52 / No. 3 - May / Jun 2001

A Doctor Shortage? Fine!, by David J. Gibson, MD - Health care professionals are behaving rationally. They are entering other fields or selecting less hostile markets.

SSVMS: Sierra Sacramento Valley Medicine - Vol. 52 / No. 2 - Mar / Apr 2001

What Comes After Managed Care?, by David J. Gibson, MD - Health care in California is broken and managed care, as a cost-containment mechanism, is dead. Employers will abandon this increasingly unpopular approach.

SSVMS: Sierra Sacramento Valley Medicine - Vol. 51 / No. 1 - Jan / Feb 2000

Corporate Practice, by David J. Gibson, MD - The long-standing bar on the corporate practice of medicine in California is being skirted in the struggle to control the structuring of health care.

SSVMS: Sierra Sacramento Valley Medicine - Vol. 52 / No. 3 - May / Jun 2001

Your Practice - 2005 A.D., by David J. Gibson, MD - In the last issue, the author contended

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managed care is dying and that employers will turn to a new way of financing health care coverage for workers. That means big changes for practicing physicians.

SSVMS: Sierra Sacramento Valley Medicine - Vol. 53 / No. 4 - Jul / Aug 2002

Plop, Plop, Fizz, Fizz, by David J. Gibson, MD - The author's family just joined Kaiser — and, as that old jingle goes, "Oh, what a relief it is!"

SSVMS: Sierra Sacramento Valley Medicine - Vol. 53 / No. 5 - Sep / Oct 2002

Thinking About Retiring? — Think Again, by David J. Gibson, MD - If you're thinking about retiring, don't forget to factor in the escalating costs of health care coverage. Then you can start worrying about long term care.

SSVMS: Sierra Sacramento Valley Medicine - Vol. 53 / No. 6 - Nov / Dec 2002

Bad Times for Physicians, by David J. Gibson, MD - Physicians in private practice will soon begin to experience a precipitous drop in office cash flow...

SSVMS: Sierra Sacramento Valley Medicine - Vol. 54 / No. 1 - Jan / Feb 2003

The Diminishing Pharmacy Benefit, by David J. Gibson, MD - Consumers can look forward to deductibles, generic drugs and on-line Canadian purchases.

SSVMS: Sierra Sacramento Valley Medicine - Vol. 54 / No. 4 - Jul / Aug 2003

"Single-Payer" Simply Won't Work in California, by David J. Gibson, MD - An increased state tax liability for expanded California entitlements would impoverish our children and their families.

SSVMS: Sierra Sacramento Valley Medicine - Vol. 54 / No. 5 - Sep 2003; Medicine's Feminization — and its Implications By David J. Gibson, MD.

SSVMS: Sierra Sacramento Valley Medicine - Vol. 54 / No. 6 - Nov / Dec 2003

CMA: Part of the Problem, by David J. Gibson, MD - The requisite for a professional is the willingness to place the calling above self-interest.

SSVMS: Sierra Sacramento Valley Medicine - Vol. 55 / No. 1 - Jan / Feb 2004

Fraud in Health Care, by David J. Gibson, MD - Despite the myth of abused doctors, fraud is a serious problem that we must address.

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Bibliography: *Organized Labor*



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Article references are linked to: <http://www.sfbctc.org/>

- **The Feminization of Medicine and its Implications** by David Gibson, M.D.
- **Workers Compensation is Under Utilized** by David J. Gibson, MD
- **An M.D. Offers Alternatives to Labor's Health Care Dilemma** by David J. Gibson, MD
- **Fraud in Health Care** by David J. Gibson, MD
- **Three Articles on Health** by Doug Perry and David J. Gibson, MD
- **Why are Prescription Drugs Cheaper in Canada?** by David Gibson, M.D.
- **Why Does Health Care Cost so Much?** by David Gibson, M.D.

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